

Message Text

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21

ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-05 /022 R

66612

DRAFTED BY: DHEW/FDA/JRWEINROTH, MD

APPROVED BY: OES/APT/BMP: MBEAUBIEN

DHEW/OIH/MACODDING

ARA/BR: AWATSON (INFO)

----- 066223

R 030000Z SEP 75

FM SECSTATE WASHDC

TO AMEMBASSY BRASILIA

UNCLAS STATE 208404

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BR

SUBJ: FDA ADVISORY - DEFECTIVE PACKAGING, LOSS OF STERILITY.

1. RDA ADVISES THAT:

PRODUCT: CORDIS DUCOR BRAND ANGIOGRAPHIC CATHETER: FEMEROL
LEFT CORONARY B, OPEN END, NO SIDE HOLES. EACH CATHETER IS
PACKAGED IN AN ENVELOPE WHICH IS MYLAR ON ONE SIDE AND SURGICAL
PAPER ON THE OTHER SIDE. THE ENVELOPE IS LABELED IN PART
"DUCOR ANGIOGRAPHIC CATHETERS STERILE. NONPYROGENIC. &&& FEMORAL-
LEFT CORONARY 2 && FRENCH 8. 100 CM. OPEN END. NO SIDE HOLES.
CATALOG NO. 524-842. GUIDE WIRE DIAMETER: .038 IN. &&& FOR ONE
USE ONLY &&& CONTENTS OF UNOPENED AND UNDAMAGED PACKAGE ARE
STERILE AND NONPYROGENIC &&& CORDIS CORPORATION, MIAMI, FLORIDA.

THE CATHETERS INSIDE THE ENVELOPES ARE PACKAGED FIVE PER BOX
WHICH IS SIMILARLY LABELED. THE BOX IS ADDITIONALLY LABELED
IN PART "&& FIVE STERILE, NONPYROGENIC DISPOSABLE UNITS &&&

PLEASE NOTE: CHARACTER "&" USED TO SYMBOLIZE ASTERICS

LOT NUMBERS:

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3045095, 3045144, 114000 (ALL CATALOG NO. 524-842) - THESE ARE
STERILIZER LOT NUMBERS AND MUST BE USED WITH CATALOG NUMBER TO
IDENTIFY THE PRODUCT.

MANUFACTURER:

THE CORDIS CORP.
3915 BISCAYNE BLVD.
MIAMI, FLORIDA 33137

REASON FOR ADVISORY: EXAMINATION OF SUBSAMPLES OF ABOVE MENTIONED
LOTS REVEALED A DEFECTIVE SEAL ON THE DISTAL END OF EACH OF 16
ENVELOPES WHICH PROVIDES AN ENTRYWAY INTO THE ENVELOPE
ITSELF. IT IS THIS ENVELOPE WHICH PROVIDES A STERILITY
BARRIER. SEVEN PATIENTS HAVE HAD REACTIONS DURING AND AFT
CATHETERIZATION WHICH MAY BE DUE TO NON STERILITY.

2. FOREIGN CONSIGNEE AS FOLLOWS:

SOCIEDAD IMPORTADORA GRASSI
RIO DE JANEIRO, BRAZIL

3. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE
IF FIRM IS AWARE OF PROBLEM OF DEFECTIVE PACKAGING. ANY
QUESTIONS FIRM MAY HAVE REGARDING DISPOSITION OF PRODUCT SHOULD
BE ADDRESSED TO CORDIS CORP. DIRECTLY.
ROBINSON

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NNN

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